

PCN129

ELICITATION OF HEALTH-RELATED QUALITY-OF-LIFE CONCEPTS ASSOCIATED WITH TRIPLE-NEGATIVE BREAST CANCER

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OBJECTIVES: Our aim was to develop a conceptual framework in patients with locally recurrent or metastatic triple-negative breast cancer (TNBC) through a literature review and patient interviews. **METHODS:** A literature review on health-related quality of life (HRQoL) in advanced breast cancer was performed using the EMBASE database. Clinical experts were asked to identify key HRQoL concepts related to TNBC. Two trained psychologists conducted semi-structured individual interviews with patients with TNBC in the UK and France until saturation of concepts was reached. Patients were asked to cite important concepts related to the impact of disease on HRQoL and to rate them. Following ISPOR guidelines, qualitative analysis was performed by coding all patient responses. Code frequency and bother ratings were used to identify salient disease and treatment impact. **RESULTS:** Two clinical experts and 28 patients were interviewed (age range, 26-83 years). Twenty-one patients (75%) had metastatic disease and 7 (25%) had locally recurrent cancer. Results of the patient interviews indicate that TNBC affects multiple dimensions of HRQoL: psychological functioning (shame/embarrassment, anger, worry, depression), role functioning (work limitation, social/leisure activities), energy levels, daily living and physical dimensions. Patients experienced distress because of fear of death, fear of disease progression, a changed body image, and concern about their loved ones. Patients associated a greater decrease in HRQoL with chemotherapy compared to radiotherapy and surgery as it resulted in a large range of impairments that impacted all relevant life domains: psychological and physical health, participation in social and occupational activities, and functioning in daily living. Coping strategies described by patients included living life day-by-day and prioritizing life differently. **CONCLUSIONS:** TNBC and its treatment have a profound effect on all aspects of patients' lives. Results of this study were used to inform the inclusion of patient-reported outcome measures in phase 3 clinical development.

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INVARIANCE OF QUALITY OF LIFE QUESTIONNAIRE EORTC QLQ-C30 IN DIFFERENT CANCER INDICATIONS

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OBJECTIVES: To validate the short version of the QLQ-C30 obtained for patients with non-small-cell lung cancer in patients with head and neck, prostate, breast or cervix cancer. **METHODS:** We analyzed data of 636 patients distributed: 237 diagnosed with head and neck cancer, 146 diagnosed with breast cancer, 140 diagnosed with cervix cancer and 113 diagnosed with prostate cancer. The analysis followed a 4-step approach. First, we conducted a Mokken nonparametric item response analysis to ascertain the QLQ-C30 dimensionality and separate several scale if appropriate. Second, we conducted a parametric Samejima's graded response model (GRM) to assess the item characteristics and information for each scale. Third, we did a confirmatory factor analysis (CFA) to test the scales unidimensionality and to obtain standardized factor loadings to suggest a reduced version of the QLQ. Finally, we assessed the discriminative validity of the reduced version by using receiver-operator curve (ROC) analysis. **RESULTS:** In this study the reduction of the general questionnaire QLQ-C30 cancer 30 items to 6 scores are obtained. First it was found that 6 scores account for a 63.38% of the overall variability. Furthermore it was found that 6 score explained 62.3% of the variability in patients with head and neck cancer Nimotuzumab tratados with a 65.53% for patients with prostate cancer treated with Nimotuzumab or CIMAvaxEGF, a 61.80% for patients with breast cancer treated with NGeGM3 and 63.83% for patients with cervical cancer treated with Nimotuzumab. 6 scores obtained correspond to the score of physical, emotional and social functional scale and the scale of symptoms of nausea and vomiting. **CONCLUSIONS:** The EORTC reduced scale was invariant for each indications of cancer studied; it presents good psychometric properties and includes a unidimensional structure of patient-perceived quality of life.

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PATIENTS' GROUPS AND ADVOCACY IN ONCOLOGY: AWARENESS, SUPPORT AND UNMET NEEDS

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OBJECTIVES: Patients' groups and advocacy play an important role in the oncology field. Understanding oncologic patients' needs may improve prevention, early detection, quality-of-life and legal rights, reducing the burden of the disease. Few studies, however, have focused on the needs of this specific population in Brazil. The present analysis can contribute to develop an awareness campaign besides advocate to cancer patient needs. Our objective was to identify and describe the main needs of cancer patients in Brazil. **METHODS:** We analyzed the PAP program database from 01/2013 to 08/2014. This is a support and personalized counseling program dedicated to cancer patients and maintained by Oncoguia Institute, an independent nonprofit institution. We retrieved and described the applicants' profiles (patient, family, specialty society, physicians, etc) and type of required information (patient rights, related to health/quality of life or access to diagnostic or treatment procedures). **RESULTS:** In the aforementioned period, 2,214 applicants received 2,586

orientations (1,683 by telephone and 903 by electronic mail). Forty-nine percent of the requests were made by the patients, 45% by a family member and 2% by health care professionals. Among all requests, 77% were regarding patient's rights and 23% were questions on health information. The 1,640 requests on patient rights were divided as follows: social rights (82%), problems related to access to treatments (10%), exams (3%) or physicians (3%). **CONCLUSIONS:** Our analysis showed that the demand for clarification regarding social rights and access to treatment reflect an unmet need for cancer patients and campaigns expanding the awareness of the population are warranted.

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INFLUENCE OF PATIENT-REPORTED OUTCOMES ON MARKET ACCESS DECISIONS IN DECENTRALIZED MARKETS (BRAZIL, ITALY, SPAIN, AND THE UNITED STATES)

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OBJECTIVES: To determine how impactful patient-reported outcome (PRO) data from clinical trial programs are on market access decision making in oncology and other disease areas in decentralized markets. **METHODS:** A review of regulatory, health technology assessment (HTA), and third-party websites and published literature was the basis for six qualitative one-on-one interviews conducted with payer decision-makers (payers) in Brazil (1), Italy (1), Spain (1), and the United States (3) in 2014. **RESULTS:** Reviews conducted of HTA content and reimbursement decisions indicate that HTA bodies have varying levels of familiarity and confidence in PRO data. All six payers indicated that it is worthwhile to collect PRO data in clinical trials for oncology, particularly in phase 3 and postmarketing studies. The payer in Spain was aware of a specific example where PRO data were crucial to decision-making for oncology. However, all six payers indicated that PRO data will increase in importance over the next 5 to 10 years and could be a key differentiator for new therapies. Payers did not differentiate the importance of PRO data by cancer type. All six payers indicated that the quality of the PRO evidence is paramount to consideration. In addition, they felt that PRO data currently have the most impact at the local level; one US payer noted there is significant opportunity to use PRO data to justify preferential product use and could be incorporated into hospital contracting. **CONCLUSIONS:** There are minimal requirements or guidelines specifically addressing whether and how health care decision-makers use PRO evidence; therefore, inclusion of PRO data in payer decision-making is currently determined on a case-by-case basis. There is growing recognition that the patient's perspective is important in market access in decentralized markets.

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THE DISCONNECT BETWEEN FUNDING DECISIONS OF CANCER DRUGS AND COMPANION DIAGNOSTIC TESTS IN CANADA

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OBJECTIVES: More and more pharmaceuticals receive indications that require the use of companion diagnostic tests to identify subgroups of patients who would benefit from the therapy. Many mutations have been identified in cancer and the choice of treatment frequently depends on the result of a specific companion diagnostic test. In Canada, the pan Canadian Oncology Drug Review (pCODR) assesses cancer drugs based on clinical evidence, cost-effectiveness and patient input, to make recommendations to Canada's provinces in guiding their funding decisions. The objective of this study is to determine how pCODR assesses drugs that require a companion diagnostic. **METHODS:** All pCODR recommendations as of were reviewed and those involving the use of a companion diagnostic were identified. Analysis of these recommendations was conducted to determine how companion diagnostic tests accompanying cancer drugs were reviewed by pCODR. **RESULTS:** pCODR has received 52 submissions since its inception and 39 recommendations have been issued. Of these recommendations, 9 involved the use of a companion diagnostic test. Both positive and negative comments around companion diagnostic tests were found among the pCODR recommendations. (Results will be tabulated) **CONCLUSIONS:** pCODR recommendations are dedicated to cancer drugs. However for those drugs requiring a companion diagnostic, pCODR also looks at the information related to these tests, e.g. costs and utility. However, there is no submission process for companion diagnostic tests at pCODR. Consequently, there is opportunity for inconsistency among the pCODR recommendations for cancer drugs and associated companion diagnostic tests.

PCN135

ARE BIOMARKERS A BIG MARKET ACCESS BONUS? US AND EU5 PAYER PERSPECTIVES AND PRESCRIBING PATTERNS FOR KEY TARGETED NON-SMALL-CELL LUNG CANCER AGENTS

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OBJECTIVES: Biomarker-driven prescribing is potentially highly cost-effective as it directs premium-priced treatment towards most-likely responders. As competition intensifies and collective treatment costs rise, however, this study examined the US and EU5 reimbursement and prescribing landscape for personalized medicines, focusing on non-small-cell lung cancer (NSCLC). **METHODS:** 100 US and 250 EU5 medical oncologists were surveyed regarding their prescribing of biomarker-driven treatments for NSCLC. In addition, 30 US managed care organization (MCO) pharmacy directors (PDs) were surveyed, and 15 reimbursement-influencing EU5 payers interviewed. **RESULTS:** Among surveyed US payers, 27% most associate biomarker-driven prescribing with premium drug pricing, versus 13% and 17% who cited high likelihood of efficacy, and focused prescribing in most-appropriate patients, respectively. Furthermore, crizotinib and afatinib are excluded/NDC blocked by the largest commercial plans of >25% of respondents, while plans of even more list these agents as non-preferred and likely to stay non-preferred, overwhelmingly due to